DEC 17 2012

5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the VertiFlex® Spinous Process Fixation Plate:

5.1 Submitted By:

VertiFlex®, Incorporated
1351 Calle Avanzado
San Clemente, California 92673

Contact: Steve Reitzler, Vice President, Clinical & Regulatory Affairs

Date Prepared: August 16, 2012

5.2 Device Name

Trade or Proprietary Name:	VertiFlex® Spinous Process Fixation Plate
Common or Usual Name:	Spinous Process Fixation Plate
Classification Name:	Spinal Interlaminal Fixation Orthosis

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate devices:

Affix™ Spinous Process Plate System (K073278; NuVasive, Inc.)

Aspen™ Spinal Fixation System (K071877, K100935; Lanx, LLC)

Axle™ Interspinous Fusion System (K101471; X-spine Systems, Inc.)

PrimaLOK™ Interspinous Fusion System (K100354; OsteoMed Spine, Inc.)

SP-Fix™ Spinous Process Fixation Plate (K102195; Globus Medical, Inc.)

Spire™ Spinous Process Plate (K032037, K043053, K102866; Medtronic, Inc.)

5.4 Device Description

The VertiFlex® Spinous Process Fixation (SPF) Plate is a one-piece bilateral locking plate device which attaches to the posterior non-cervical spine by securely grasping two adjacent spinous processes. The SPF Plate is available in multiple sizes to accommodate different anatomical requirements, and it is composed entirely of titanium 6AL-4V alloy. The SPF Plate may be implanted by either conventional surgical methods, or via minimally-invasive techniques. Proprietary manual instrumentation for implantation of the SPF Plate is available for both conventional and minimally-invasive surgical procedures.

5.5 Intended Use

The subject device is indicated for use as follows:

The VertiFlex® Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1 - S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: Degenerative disc disease (defined as back pain of discogenic origin with degenerationof the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The VertiFlex® Spinous Process Fixation Plate is intended for use with bone graft, and is not intended for stand-alone use.

5.6 Comparison to Predicate Devices

Testing and comparisons of design characteristics and features have established that the subject SPF Plate is substantially equivalent in design, materials of composition, indications, performance, and other features, to other predicate spinous process fixation devices commercially available in the U.S.

5.7 Summary of Non-Clinical Tests

Non-clinical tests conducted in accordance with such recognized standards as ASTM F1717-12, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*, static pull-off testing in synthetic bone, and static dissociation testing, have demonstrated the substantial equivalence of the subject SPF Plate to a commercially-available predicate in terms of performance.

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of all testing and comparison demonstrated the substantial equivalence of the subject SPF Plate to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2012

VertiFlex®, Incorporated
% Mr. Steve Reitzler
Vice President, Clinical & Regulatory Affairs
1351 Calle Avanzado
San Clemente, California 92673

Re: K122509
Trade/Device Name: VertiFlex® Spinous Process Fixation Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 11, 2012
Received: December 12, 2012

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122509

Device Name: VertiFlex® Spinous Process Fixation Plate

Indications for Use:

The VertiFlex® Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device intended for use at a single level in the non-cervical spine (T1 - S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: Degenerative disc disease (defined as back pain of discogenic origin with degenerationof the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The VertiFlex® Spinous Process Fixation Plate is intended for use with bone graft, and is not intended for stand-alone use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices
510(k) Number: K122509